

REMARKS

Claims 36-43 are added to the application. Thus, Claims 9, 11, 12, 15, 17-19, 21, 25, 35-43 are pending. Further to the interview summary of April 27, 2005, Applicant imported allowed polypeptide claims (now claims 36-43) from US App. No. 09/027,887 into the present case. Concurrently, Applicant is expressly abandoning related case US App. No. 09/027,887 ("the '887 Application").

As the interview summary correctly suggests, polypeptide and polynucleotide claims were subject to restriction requirements in parent cases, including US App. No. 07/094,307 on July 5, 1989, US App. No. 07/232,482 on February 27, 1991, US App. No. 08/034,460 on June 16, 1993, and US App. No. 08/468,679 (now USPN 5,773,600) on September 4, 1996. Thus, the protein and DNA claims are separately patentable. The great-grandparent (US App. No. 07/094,307) and grandparent (US App. No. 07/232,482) cases contained a further restriction to the vaccine from the DNA claims and the protein claims, but this restriction was lifted in the parent case (US App. No. 08/034,460) where the protein and vaccine claims were included in the same group (Group II). Additionally, the present case was not subject to a restriction requirement and contained both protein and vaccine claims since the preliminary amendment, filed on September 9, 1996. Thus, the inclusion of the vaccine and protein claims and exclusion of DNA claims in the present case is proper.

35 U.S.C. § 121, states in part, "A patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such a requirement, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application or against the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the application." Thus, only polypeptide and vaccine claims are pending in the present

application, rendering moot the double patenting rejection in the Action. New claims 36-43 are substantially similar to claims of co-pending '887 Application, which claims were deemed allowable in a January 14, 2005 Office Action. The claim correspondence is (new claim to '887 Application claim): 36 to 41; 37 to 42; 38 to 44; 39 to 45; 40 to 46; 41 to 47; 42 to 50; and 43 to 51. Applicant respectfully asserts that all pending claims are allowable.

The Action requires new drawings in compliance with the Draftsperson's Notice of June 29, 1995. The new drawings are attached and incorporate the change to Fig. 7 referenced above in the Amendments to the Drawings.

The Action also requests a sequence listing complying with all the requirement of 37 CFR §§ 1.821-1.825, which includes SEQ ID NO: 27. In response, Applicant submits herewith a substitute sequence listing containing the 27 sequences in the application, including SEQ ID NO: 27 with the correction of "HisGlyAlaGlyAspSer" between amino acids 193 to 198 to "ArgMetAlaProValIleGly." A computer readable format accompanies the hard copy of the substitute sequence listing as required under 37 C.F.R. § 1.825 (b).

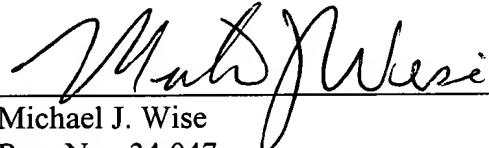
CONCLUSION

Applicants believe the claims are now in condition for allowance. If any additional fee is due, the Commissioner is authorized to charge such fees to Perkins Coie's Deposit Account No. **50-2586**. If anything can be done to further this application, please contact the undersigned at 310-788-9900.

Respectfully submitted,

PERKINS COIE LLP

By:


Michael J. Wise
Reg. No. 34,047

Dated: July 11, 2005

Cust. No. 34055

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Amendments to the Drawings:

The attached sheets of drawings, which have been corrected in accordance with Notice of Draftsperson's Patent Drawing Review dated June 29, 1995, include a change to Figure 7. An annotated sheet showing the requested change to Figure 7 and a replacement sheet for Figure 7 are attached.

In Figure 7, the six amino acids 193 to 198, previously "HisGlyAlaGlyAspSer," have been replaced with the seven amino acids "ArgMetAlaProValIleGly." The present invention is directed to mutations to the pertussis toxin S1 subunit, which reduce toxicity yet retain an immunoprotective epitope. Prior to Applicant's invention, the S1 subunit sequence was disclosed in Nicosia *et al*, 1986, Proc. Natl. Acad. Sci. USA 83: 4631-4635 ("Nicosia publication") in Fig. 2 on page 4632. Pursuant to 37 C.F.R. §§ 1.84 and 1.121(d), Applicant requests a drawing change in Figure 7 to delete amino acids 193 to 198, currently "HisGlyAlaGlyAspSer," and replace those six amino acids with the seven amino acids of "ArgMetAlaProValIleGly." The sequence with the replaced portion is identified in the Nicosia publication and incorporated by reference in the instant specification. The proposed change is shown in red ink. Those skilled in the art will note that the proposed sequence substitution causes the amino acid reference position numerals to correspondingly shift downstream starting from position 200. For purposes of clarity, such a shift has not been shown in red ink.

No new matter has been added by this amendment. Pursuant to MPEP § 608.01(p) and MPEP § 2163.07(b), Applicant may replace material incorporated by reference without adding new matter. Here, Applicant incorporated by reference the Nicosia publication in the specification on page 2, lines 10-11; page 9, lines 5-6; and page 16, lines 12-14. The Nicosia publication contains the above-identified substitute sequence. Accordingly, this information is "as much a part of the application as filed as if the text were repeated in the application, and

should be treated as part of the text of the application as filed. Hence, replacing the identified material incorporated by reference with the actual text is not new matter." MPEP § 2163.07(b).

Attachments: Annotated Sheet Showing Change to Fig. 7

Replacement Sheets for Fig. 1, Figs. 2A-B, Fig. 3, Fig. 4, Fig. 5, Fig. 6, Fig. 7, Fig. 8A, Fig. 8B, Fig. 9, Fig. 10, Figs. 11A-F, and Figs. 11G-J



Appl. No. 08/448,727
Amendment Dated July 11, 2005
Reply to Office Action of January 26, 2005
Annotated Sheet Showing Change

1 10 20
MetValProProAlaThrValTyrLysTyrAspSerArgProProGluAspValPheGln

21 30 40
AsnGlyPheThrAlaTrpGlyAsnAsnAspAsnValLeuAspHisLeuThrGlyArgSer

41 50 60
CysGlnValGlySerSerAsnSerAlaPheValSerThrSerSerArgArgTyrThr

61 70 80
GluValTyrLeuGluHisArgMetGlnGluAlaValGluAlaGluArgAlaGlyArgGly

81 90 100
ThrGlyHisPheIleGlyTyrIleTyrGluValArgAlaAspAsnAsnPheTyrGlyAla

101 110 120
AlaSerSerTyrPheGluTyrValAspThrTyrGlyAspAsnAlaGlyArgIleLeuAla

121 130 140
GlyAlaLeuAlaThrTyrGlnSerGluTyrLeuAlaHisArgArgIleProProGluAsn

141 150 160
IleArgArgValThrArgValTyrHisAsnGlyIleThrGlyGluThrThrThrGlu

161 170 180
TyrSerAsnAlaArgTyrValSerGlnGlnThrArgAlaAsnProAsnProTyrThrSer

181 190 200
ArgArgSerValAlaSerIleValGlyThrLeuValHisGlyAlaGlyAspSerAlaCys

201 210 220
MetAlaArgGlnAlaGluSerSerGluAlaMetAlaAlaTrpSerGluArgAlaGlyGlu

221 230 234
AlaMetValLeuValTyrTyrGluSerIleAlaTyrSerPhe

FIGURE 7

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

Walter N. Burnette, III

Serial No.: 09/027,887

Filed: February 23, 1998

For: RECOMBINANT DNA-DERIVED
BORDETELLA TOXIN SUBUNIT
ANALOGS

Group Art Unit: 1631

Examiner: John Brusca

I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is being deposited this day, July 11, 2005, with the United States Postal Service as first class mail in an envelope addressed to Mail Stop Amendment, Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450.

Dee Dee Sutherland
DEE DEE SUTHERLAND

EXPRESS ABANDONMENT UNDER 37 CFR §1.138

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Applicant requests express abandonment of the above-referenced application under 37 CFR §1.138 as of the date of filing this paper. Applicant abandons the application without prejudice to further prosecution of both the claims and subject matter contained therein.

Respectfully submitted,

PERKINS COIE LLP

By: *Lauren Sliger*
Lauren Sliger
Reg. No. 51,086

Dated: July 11, 2005

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Please acknowledge receipt of the following by affixing hereon the Patent and Trademark Office date stamp and returning this card to our office.

Applicant: Walter N. Burnette, III
Application No.: 09/027,887
For: RECOMBINANT DNA-DERIVED BORDETELLA TOXIN
SUBUNIT ANALOGS
Filed: February 23, 1998

EXPRESS ABANDONMENT UNDER 37 CFR § 1.138

Attorney(s): Michael J. Wise
Our Reference: 54113.8010.US00
Date of Deposit: July 14, 2005 (via First Class Mail)
Enclosure(s): Express Abandonment Under 37 CFR § 1.138; return postcard

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